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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,268

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Jeffrey William Mochlenbruck

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EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/812,268

Applicant(s)

MOEHLENBRUCK ET AL.

Examiner

Marsha M. Tsay

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 40-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/01/04; 03/07/05</u> | 6) <input type="checkbox"/> Other: ____ |

Claims 1-39, 52-59 are canceled. Claims 40-51 are pending and currently under examination.

Priority: The priority date is April 7, 2000, for the purpose of prior art.

Claim Objections

Claims 41, 44 are objected to because of the following informalities: in claim 41, the colon denoting high salt:high sucrose should be corrected to "to" or "and"; in claim 41, the article "A" of "The" should precede the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 40, step (2), the use of the term "containing" does not make sense. The term should be replaced by another term such as "embedding" or "inserting" or another appropriate term since it appears as if the hydrogel is being placed within the semipermeable membrane.

Regarding claims 40, 43, 45, 47, 49, the phrase "substantially" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed

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(those encompassed by "substantially"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 41-42, 44, 46, 48, 50-51 are included in this rejection because they are dependent on the above claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechanic (US 5854397). Mechanic discloses a process for cross-linking a proteinaceous material, including collagen, collagen fibrils, and collagen matrices (col. 4 lines 15-16). According to Mechanic, the term proteinaceous material includes both proteins such as collagen and protein-containing materials such as tissue (col. 4 lines 19-20). Generally, the particular proteinaceous material utilized as the starting material is determined by the intended use of the product, i.e. if the intent is to build a heart valve then it is preferred that the starting material has a high collagen content such as pericardium (col. 4 lines 20-25). The proteinaceous material is "preconditioned" before irradiation, meaning the proteinaceous materials is soaked in a first media solution and irradiated in the second (col. 5 line 1). As a result, the proteinaceous materials are better cross-linked, show improved mechanical properties and decreased susceptibility

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to proteolytic degradation (col. 5 lines 1-4). Mechanic discloses solutions of high osmolality are generally used for the first media solution, i.e. sodium, chloride, potassium buffers, and Good's buffers, where in the osmolality have been increased by addition of a solute, such as sucrose (col. 5 line 10). In working examples 1-10, Mechanic discloses proteinaceous materials from different sources to be crosslinked, including pericardium tissue, collagen fibrils, and collagen (col. 8-13). In example 8, rat type I collagen was divided into six samples and each sample was placed in a dialysis bag with 300 mg NaCl (col. 12 line 35-37). Samples 5-6 were dialyzed into phosphate buffered saline pH 7.4 including 50% sucrose, and 0.2% methylene blue (col. 12, lines 40-41) and then exposed to a white floodlight while holding the temperature between 8° and 12°C (col. 12, lines 45-50). Mechanic does not teach nucleus pulposus tissue or type II collagen.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the process of Mechanic and replace the starting material with nucleus pulposus tissue filled in with type II collagen for disc regeneration purposes because Mechanic teaches that the particular proteinaceous material used as the starting material is determined by the intended use of the product (see column 4) and here the intended use is intervertebral disc regeneration wherein said disc is naturally made of mucoïd nucleus pulposus tissue naturally comprising collagen type II (claims 40, 43, 44, 47-51).

It would also have been obvious to one of ordinary skill in the art at the time the invention was made to cross-link type II collagen from nucleus pulposus tissue by the

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method of Mechanic, wherein the nucleus pulposus tissue is placed in a dialysis bag and submerged in a high salt to high sucrose solution for a period of between 24 to 72 hours, if necessary, because Mechanic discloses that the starting material for the proteinaceous materials that are to be cross-linked by photooxidation is determined by the intended use of the product and can therefore encompass various types of tissues that contain protein and/or collagen (claims 41, 42, 45-46). The motivation to submerge the collagen tissue in a dialysis bag and in a high salt/high sucrose solution for a period of 24 to 72 hours is also given by Mechanic which discloses a "preconditioning" period of the tissue prior to irradiation will result in better cross-linking, improved mechanical properties, and decreased susceptibility of the collagen tissue to proteolytic degradation. One of ordinary skill in the art would recognize the time period for the "preconditioning" process can be adjusted, along with the size of the dialysis tubing, in order to produce the optimum cross-linked collagen product (claims 42, 46).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 31, 2006

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PRIMARY EXAMINER